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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,330

03/25/2004

Eitan Konstantino

021770-000120US

8217

20350 7590 03/19/2010  
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EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

03/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/810,330	<b>Applicant(s)</b> KONSTANTINO ET AL.	
	<b>Examiner</b> Victor X. Nguyen	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 60-64, 69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-64, 69 and 70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. This Office action is in response to the communication filed on 12/7/2009.
2. Accordingly, claims 60-64 and 69-70 are pending in this present application.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 60-62, 64, and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by March et al 5,306,250.

Claims 60-62: March et al disclose a method for delivering a drug to a blood vessel lesion, said method comprising: inflating a balloon 46 to radially expand a scoring structure comprising metal scoring elements 56 carried by said balloon (fig. 2), wherein the balloon inflation engages the scoring elements against stenotic material in the lesion 28 to radially penetrate the stenotic material (see col. 3, lines 34-46); and releasing a drug (see col. 4, lines 14-26) into the scored lesion to enhance delivery into the vessel wall; wherein the drug is carried by the balloon 46 as a platform, and wherein releasing comprises embedding the drug through the stenotic material into the vessel wall (see col. 4, lines 14-26).

Claim 64: March et al disclose the drug is present in a drug containing polymer (col. 5, lines 43-50).

Claims 69-70: March et al disclose the metal scoring elements are included in a scoring cage 54 slidably carried to the balloon, where the scoring elements in the scoring cage are arranged helically 56 over the expansible balloon.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over March et al. With regard to claim 63, March et al disclose the invention substantially as claimed, but he is silent regarding the drug is present in capsules. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug which is present in capsules, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use or as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 60-64 and 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruiz 5,868,779 in view of Dror et al 5,102,402.

Claim 60: Ruiz discloses inflating a balloon 12 to radially expand a scoring structure comprising metal scoring elements (item 14, see col. lines 21-28) carried by said balloon (fig.3), wherein the balloon inflation engages the scoring elements against stenotic material in the lesion 28 to radially penetrate the stenotic material (see col.2, lines45-66). Ruiz does not disclose releasing a drug into the scored lesion. However, Dror et al teach releasing a drug into the

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scored lesion (see col. 2, lines 31-37) in order to produce affecting drugs or diagnostic materials exactly where it is needed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method taught by Ruiz with the releasing a drug into the scored lesion as suggested by Dror so that it too would have the same advantage. As to claims 61-64, Dror teaches the drug is carried by the balloon 12 as a platform, where the drug is present in capsules 16 or in a drug containing polymer (see col. 2, line 11).

Claims 69-70: Ruiz discloses the metal scoring elements 14 are included in a scoring cage (fig. 3) slidably carried to the balloon, where the scoring elements in the scoring cage are arranged helically 56 over the expansible balloon.

### ***Response to Arguments***

5. Applicant's arguments filed 12/7/2009 have been fully considered but they are not persuasive. Applicants state that The March device fails to suggest a balloon is expanded by inflation and does not teach a scoring element that can either engage or penetrate stenotic material. Examiner disagrees. In fact, as seen in figures 1-3 of March discloses a balloon 46 (see col. 5, lines 55-57; col. 6, lines 1-5) is expanded by inflation and does teach a scoring element 56 that can either engage or penetrate stenotic material (see col. 6, lines 1-15, and lines 38-41). Furthermore, the applicants failed to point out any arguments regarding to the rejection of claims 60-64 and 69-70 as being unpatentable over Ruiz in view of Dror. Therefore, the it is taken as admission that the above rejections can still sustain and claims 60-64 and 69-70 as being unpatentable over Ruiz in view of Dror also stand.

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VN /

Examiner, Art Unit 3731

3/10/2010

/Gary Jackson/

Supervisory Patent Trainer

TC 3700

March 14, 2010